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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,359	01/19/2001	Lola M. Reid	320727.50601	7133

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KATTEN MUCHIN ROSENMAN LLP
525 WEST MONROE STREET
CHICAGO, IL 60661-3693

EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/764,359	REID ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-10,12-34,37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) *10,22 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-4, 6-9, 12-21, 23-34 and 39-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/05 has been entered.

Amended claims 1, 3-4, 6-10, 12-34, 37 and 39-40 are pending in the present application.

Applicants' amendment filed on 11/26/03 has been entered.

Applicants further elected the following species: (a) liver as a donor tissue; (b) adult as a donor; and (c) hepatic progenitor cell lineage as a species of progenitor cell lineage in the amendment filed on 1/16/03.

Therefore, claims 10, 22 and 37 are withdrawn because they are directed to non-elected species.

Response to Amendment

The rejection under 35 U.S.C. 102(b) as being anticipated by Reid et al. (WO 95/13697; 1995; IDS) is withdrawn in part in light of Applicants' amendment.

The rejection under 35 U.S.C. 102(e) as being anticipated by Faris (U.S. 6,129,911) is withdrawn in part in light of Applicants' amendment.

The rejection under 35 U.S.C. 103(a) as being unpatentable over Reid et al. (WO 95/13697; 1995; IDS) in view of Faris (U.S. 6,129,911) is withdrawn in light of Applicants' amendment.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-7, 16-21, 23-34 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***This is a new ground of rejection necessitated by Applicants' amendment.***

Claims 1, 16, 21, 23 and their dependent claims recite the limitations "greater than about 2 hours postmortem". There is literally **no written support** for this limitation which encompasses any time frame greater than about 2 hours postmortem, for examples 4 hrs, 6 hrs, 24 hrs as well as 48 hrs, 72 hrs, 96 hrs and weeks or months postmortem. The originally filed specification teaches that the tissues are harvested preferably within about 6 hrs after the donor's heartbeat ceased, and the sooner the tissue is harvested after the donor's heartbeat ceased the better, including within about 45, 30, or 15 minutes after the donor's heartbeat ceased (page 5, lines 13-20). **Thus,**

it is apparent that Applicants do not specifically contemplate to exclude obtaining any donor tissue less than about 2 hours postmortem. The originally filed specification further teach that the livers obtained postmortem at different times but preferably within at least 24 hours, **with a maximum of 30 hours** (page 46, lines 11-12). **Thus, it is apparent that Applicants did not contemplate obtaining any donor tissue greater than 30 hours post-mortem for processing at the time the application was filed**. Applicants asserted that paragraphs 186 and 14 (please refer any support in the future by page number and line number because the specification does not have numbered paragraphs) support the new limitation "greater than about 2 hours postmortem", however, the examiner could not find such a support. Furthermore, the original claims 33-35 recite "within about six hours after the heartbeat ceased", "within about three hours after the heartbeat ceased" and "within about two hours after the heartbeat ceased", respectively, also do not literally support a concept of obtaining any donor tissue greater than 30 hours post-mortem or excluding any donor tissue lesser than about 2 hours postmortem as encompassed by the new limitation "greater than about 2 hours postmortem". Therefore, given the lack of guidance provided by the originally filed specification, it would appear that Applicants did not contemplate or have possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 8-9, 12-15, 21 and 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection.***

Claims 3-4, 8-9 and 12-15 are dependent on the cancelled claim 2. Therefore, it is unclear what exactly do Applicants intend to claim. The metes and bounds of these claims are not clearly determined.

In claims 21, 23 and their dependent claims the recited method steps do not relate or lead to the preambles recited in the claims. This is because the harvested tissue is further processed to obtain progenitor cells or a population of cells enriched in diploid cells, and thus there would not be any liver tissue having at least one progenitor cell population or at least one diploid cell population to be provided. Clarification is requested because the metes and bounds of the claims are not clearly determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Reid et al. (WO 95/13697; 1995; IDS). ***This is a modified rejection.***

With respect to the elected species, Reid et al. disclose methods for isolating hepatoblasts comprising liver stem cells (pluripotent precursors) and committed precursors for either hepatocytes and bile duct cells using panning technologies and multiparametric FAC sorting from a single cell suspension of liver cells (see Summary of Invention). Reid et al. state "The methods of the invention have been developed using embryonic and neonatal livers from rats, however, the method of the invention offers a systemic approach to isolating hepatoblasts from any age from any species" (page 4, lines 6-10). This statement includes the isolation of hepatoblasts from adult liver (see page 43). Reid et al. also note that hepatoblasts which are found in a high proportion of liver cells in early embryonic livers and in small number located periportally in adult livers (page 3, line 35 continues to line 1 of page 4). Reid et al. also teach that the tendency of the isolated cells to aggregate is prevented by maintaining the cells at 4^0C and by removing calcium with EGTA (page 39, lines 24-33).

The isolated hepatoblast cell populations prepared by the methods taught by Reid et al. are indistinguishable from the composition comprising a population of cells enriched in diploid cells, including progenitors that express alpha-fetoprotein of the presently claimed invention. Please, also note that where, as here, the claimed and prior art products are identical or substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the

prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the instant claims are anticipated by WO 95/13697.

Response to Arguments

Applicants' argument related to the above rejection in the Amendment filed on 3/24/05 (pages 8-10) has been fully considered, but it is not found persuasive.

With respect to composition claims 39-40, Applicants argue basically that Reid does not teach or suggest a method of obtaining progenitor cells from tissue obtained greater than about 2 hours postmortem. However, Applicants failed to provide any objective evidence that distinguish the isolated hepatoblast cell populations prepared by the methods taught by Reid et al. from any of the claimed compositions of the present invention. As already noted above, the claimed and prior art products are identical or substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie

obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the instant claims are anticipated by WO 95/13697 for the reasons set forth above.

Claims 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Faris (U.S. 6,129,911 with the effective filing date of 7/10/1998). ***This is a modified rejection.***

With respect to the elected species, Faris teach methods for isolating liver cell clusters comprising a liver stem cell and a hepatocyte, and a population of isolated liver stem cells, wherein the stem cells can differentiate into hepatocytes or bile ductal cells (see Summary of the Invention). The isolated liver cell clusters and isolated stem cells are obtained from adult liver tissue from various species such as a mouse, a pig or a human; and that the liver tissue is obtained from deceased donors or cadavers (these donors do not have heart-beats, see col. 5, lines 3-25). Faris teaches that the liver cell clusters are dissociated by enzymatic disruption to destroy the desmosomal junctions, and that the isolated liver stem cells can be further purified using magnetic beads coated with antibodies specific for selective cell markers or FACS sorting (col. 6, lines 54-67).

The isolated liver cell clusters and liver stem cells are indistinguishable from the composition comprising a population of cells enriched in diploid cells, including progenitors that express alpha-fetoprotein of the presently claimed invention. Please, also note that where, as here, the claimed and prior art products are identical or substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the instant claims are anticipated by Faris.

Response to Arguments

Applicants' argument related to the above rejection in the Amendment filed on 3/24/05 (pages 9-11) has been fully considered, but it is not found persuasive.

With respect to composition claims 39-40, Applicants argue basically that Faris does not teach or suggest a method of obtaining progenitor cells from tissue obtained greater than about 2 hours postmortem. However, Applicants failed to provide any objective evidence that distinguish isolated liver cell clusters and liver stem cells

prepared by the methods taught by Faris from any of the claimed compositions of the present invention. As already noted above, the claimed and prior art products are identical or substantially identical, **or** are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the instant claims are anticipated by Faris for the reasons set forth above.

Conclusions

No claims are allowed.

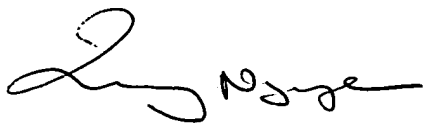
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.



QUANG NGUYEN, PH.D
PATENT EXAMINER